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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,085	01/12/2001	Jaap Goudsmit	9250-28CT	3169
20792	7590	11/01/2005	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 11/01/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/760,085	Applicant(s) GOUDSMIT ET AL	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-21, 28-31, 39-41 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21, 28-31, 39-41 and 43 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/18/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 1/18/2005 has been entered.

Claims 16-21, 28-31, 39-41 and 43 are pending.

Claim Objections

2. Claim 43 is objected to because of the following informalities: claim 43 depends from the canceled claim 42. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 16-21, 28-31, 39-41 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Bastian et al. (WO 95/21849 (US 6,180,778 used herein as translation)).

Bastian et al. disclose a method of separating nucleic acid mixture into their double stranded and single stranded fraction. All nucleic acids are simultaneously adsorbed in a mineral substrate, then separated by fractional elution into double stranded and single stranded nucleic acids, or double stranded and single stranded nucleic acid of a sample are selectively adsorbed in a mineral substrate (See the Abstract). The double stranded nucleic acid predominantly binds to the first mineral support and after optionally performed washing steps, can be eluted under conditions for low ionic strength or with water (See column 3, lines 23-28). The non-adsorbed single-stranded nucleic acid collected are subsequently adjusted and can be adsorbed to a second mineral support and become eluted under conditions of low ionic strength or with water (column 3, lines 30-36). The treatment condition contains a chaotropic substance (See column 4, lines 12-16). The mineral support consists of porous or non-porous metal oxides, silica gel or glass (See column 6, lines 6-21). The particle size is 0.1 μm to 1000 μm (See column 6, lines 6-12). For binding double stranded nucleic acid to mineral supports, the solution contains guanidinium thiocyanate with concentration 1 to 8 M and EDTA with the concentration from 5 mM to 200mM (See column 6, lines 49-58). Centrifuge is involved for pelletizing the silica material (See column 8, lines 53-54). Magnesium chloride, in concentration of from 0.1 to 10M may also be in combination for lysing or binding the sources containing nucleic acids (See column 5, lines 61-67 and column 15, claims 11-14). The complexes comprise alkaline earth metal ions bound to EDTA (See column 16, claim 22). Since the language "consisting essentially of" is considered to be open language, and in the specification, there is no clearly indication that alcohol is not allowed in the purification procedure, the teachings of Bastian et al. anticipate the limitations of claims 16-21, 28-31, 39-41 and 43.

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For the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are “consisting essentially of” will be constructed as equivalent to “comprising”. See e.g. PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase consisting essentially of for purpose of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”).

If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicants invention. In re De lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA1964). See also ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Accordingly, for the purposes of prior art, the claim limitation “consisting essentially of” is read as comprising and does not exclude the use of alcohol.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J.T.*
October 13, 2005

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

10/24/05